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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/903,396
Filing Date	July 10, 2001
First Named Inventor	KEITH D. ALLEN
Art Unit	1632
Examiner Name	Valerie E. Bertoglio
Attorney Docket Number	R-359

Total Number of Pages in This Submission

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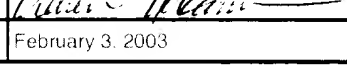
ENCLOSURES (*Check all that apply*)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Aaron T. Hokamura
Signature	
Date	February 3, 2003

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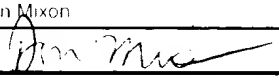
Signature		Date	February 3, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Keith D. ALLEN

Group Art Unit: 1632

Serial No.: 09/903,396

Examiner: Bertoglio, Valerie E.

Filed: July 10, 2001

Attorney Docket No.: R-359

For: TRANSGENIC MICE CONTAINING GLUCOCORTICOID-INDUCED RECEPTOR GENE DISRUPTIONS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office communication mailed October 3, 2002, concerning the Examiner's restriction of the claims, Applicant hereby provisionally elects, with traverse, Group III (claims 8, 17-23, 25 and 33), drawn to a transgenic animal comprising a disruption in a glucocorticoid-induced receptor gene.

In the restriction, the Examiner asserts that claims 1-35 are drawn to eight distinct subjects, grouped as: Invention I (claims 1-4), drawn to a nucleic acid construct and methods of making the construct; Invention II (claims 5-7, 9 and 26), drawn to cells with a disruption in a glucocorticoid-induced receptor gene; Invention III (claims 8, 17-23, 25 and 33), drawn to a transgenic animal comprising a disruption in a glucocorticoid-induced receptor gene; Invention IV (claims 11, 12 and 27-29), drawn to methods of using a transgenic animal comprising a disruption in a glucocorticoid-induced receptor gene to test agents; Invention V (claims 10 and 24), drawn to a method of making a transgenic animal; Invention VI (claims 13-15, 30 and 31), drawn to methods of using cells with a disruption in a glucocorticoid-induced receptor gene to test agents; Invention VII (claims 16, 32 and 34), drawn to an agent; and Invention VIII (claim 35), drawn to a database.

Specifically, the Examiner asserts that the claims of Invention I and Invention II are patentably distinct in that the nucleic acid construct of Invention I can be used as a probe while the cells of Invention II can be used in *in vitro* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's conclusion. Applicant

believes that a reasonable search or examination of the prior art would produce results related to the subject matter of both invention groups, and would not put serious burden on the Examiner.

The Examiner further asserts that the claims of Inventions I and III are patentably distinct because the construct can be used as a probe while the transgenic animal can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion. A search or examination of the prior art conducted on one of these aspects *e.g.* production of glucocorticoid-induced receptor-deficient transgenic animals, would produce results that would encompass transgenic animals and the nucleic acid construct. Thus, the additional burden of a separate search or examination would not be required.

It is also asserted by the Examiner that the claims of Invention I and Invention IV are patentably distinct because the construct can be used as a probe while the method can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion in that the construct of Invention I and the method of invention IV are related and therefore a search or examination of these claims can be made without serious burden on the Examiner.

The Examiner also asserts that the claims of Inventions I and V are patentably distinct because the nucleic acid construct can be used as a DNA probe. The Applicant disagrees with the Examiner's conclusion. A search or examination of the prior art conducted on the subject matter of Inventions I and V would produce results encompassing glucocorticoid-induced receptor nucleic acid constructs and methods of producing transgenic animals. Thus, a search or examination of these claims would not seriously burden the Examiner.

The Examiner further asserts that the claims of Invention I and Invention VI are patentably distinct because the construct can be used as a probe while the method can be used in *in vitro* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion in that the construct of Invention I is related to the methods of Invention VI and therefore, a search or examination of these claims would not unduly burden the Examiner.

The Examiner also asserts that the claims of Inventions I and VII are patentably distinct because the nucleic acid construct of Invention I can be used as a probe while the agent of Invention VII can be used to modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion. The construct of Invention I and the agent of Invention VII are related and, thus, a search or examination of these claims would not seriously burden the Examiner.

It is also asserted by the Examiner that Inventions I and VIII are patentably distinct because the nucleic acid construct of Invention I can be used as a probe while the database of Invention VIII can be used for statistical analysis. The Applicant disagrees with the Examiner's assertion in that the claims of Inventions I and VIII are related. Therefore, a search or examination of these claims would not unduly burden the Examiner.

Further, the Examiner asserts that the claims of Invention II and Invention III are patentably distinct because the cells can be used in *in vitro* assays to determine differential gene expression while the transgenic animals can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion. A search or examination of the prior art conducted on this subject matter, *i.e.*, glucocorticoid-induced receptor disruptions, would produce results encompassing both cells and animals with disruptions in glucocorticoid-induced receptors. Thus, the burden of an additional separate search or examination would not be required.

The Examiner also asserts that Inventions II and IV are patentably distinct because the cells of Invention II can be used in *in vitro* assays to determine differential gene expression while the method of Invention IV can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion in that the claims of Invention II are related to the claims of Invention IV. Therefore a search or examination on these claims would not unduly burden the Examiner.

The Examiner further asserts that the claims of Inventions II and V are related as product and process of use, and therefore distinct inventions. The Applicant disagrees with the Examiner's assertion. A search or examination of the prior art conducted on this subject matter, *i.e.*, glucocorticoid-induced receptor disruptions, would produce results encompassing both cells and methods of making transgenic animals with disruptions in glucocorticoid-induced receptors. Thus, the burden of an additional separate search or examination would not be required.

Also, the Examiner asserts that the claims of Inventions II and VI are related as product and process of use. The Examiner states that the method of testing agents can be done *in vivo* using transgenic animals comprising a disruption in glucocorticoid-induced receptors while the cells can be used in *in vitro* assays to determine differential gene expression between cells. The Applicant disagrees with the Examiners assertion. The claims of Inventions II and VI are related. Thus, a search or examination of the prior art related to the subject matter of Invention II and Invention VI would not place an undue burden on the Examiner.

The Examiner asserts that Inventions II and VII are patentably distinct because the cells of Invention II can be used in *in vitro* assays to determine differential gene expression while the agent of Invention VII can be used to modulate glucocorticoid-induced receptor expression. The Applicant disagrees. The claims of Invention II and the claims of Invention VII are related. Therefore search of examination of these claims would not unduly burden the Examiner.

It is also asserted by the Examiner that Inventions II and VIII are patentably distinct because the cells of Invention II can be used to isolate protein while the database of Invention VIII can be used for statistical analysis. The Applicant disagrees with the Examiner's assertion in that the claims of Inventions II and VIII are related. Therefore, a search or examination of these claims would not unduly burden the Examiner.

The Examiner further asserts that the claims of Inventions III and IV are related as product and process of use. The Examiner states that the method of testing agents can be done *in vitro* using cells comprising a disruption in a glucocorticoid-induced receptor. The Applicant disagrees with the Examiner's assertion in that the claims of Invention III are related to the claims of Invention IV, and therefore a search or examination of these claims would not unduly burden the Examiner.

The Examiner also asserts that the claims of Invention III and V are related as a process of making and a product made. The Examiner further asserts that the transgenic animal of Invention III can be made by implanting the blastocyst with DNA. The Applicant disagrees with the Examiner's assertion. A search or examination of the prior art conducted on this subject matter, *i.e.*, glucocorticoid-induced receptor disruptions, would produce results encompassing both transgenic animals and methods of making transgenic animals with disruptions in glucocorticoid-induced receptors. Thus, the burden of an additional separate search or examination would not be required.

Further, the Examiner asserts that Inventions III and VI are patentably distinct because the transgenics can be used to determine the role of glucocorticoid-induced receptors *in vivo* while methods of using the cells are process steps with the purpose of identifying agents. The Applicant disagrees in that the claims of Invention III are related to the claims of Invention VI. Therefore a search or examination on these claims would not seriously burden the Examiner.

The Examiner further asserts that Inventions III and VII are patentably distinct because the transgenic animals can be used to determine the role of glucocorticoid-induced receptor *in vivo* while the agent is used to modulate glucocorticoid-induced receptor. The Applicant disagrees in that the claims of Invention III are related to the claims of Invention VII. Therefore a search or examination on these claims would not seriously burden the Examiner.

The Examiner also asserts that the claims of Inventions III and VIII are patentably distinct because the methods of Invention III can be used to make a nucleic acid construct while the database of Invention VIII can be used for statistical analysis. The Applicant disagrees with the Examiner's assertion in that the claims of Inventions III and VIII are related and therefore a search or examination on these claims can be performed without serious burden to the Examiner.

It is further asserted by the Examiner that the methods of each of Inventions IV-VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical consideration and requires materially distinct protocols and reagents. The Applicant disagrees with the Examiners assertion. The claims of Inventions IV-VI are related. Therefore, a search or examination of these claims would not unduly burden the Examiner.

The Examiner further asserts that Invention IV and Invention VII are patentably distinct because the agent can be idenitified from *in vitro* assays sing cells harboring a disruption in glucocorticoid-induced receptors. The Applicant disagrees with the Examiner in that the claims of Inventions IV and VII are related and therefore a search or examination would not seriously burden the Examiner.

The Examiner further asserts that Inventions IV, V or VI and Invention VIII are patentably distinct because the methods of Inventions IV, V or VI do not require the database of Invention VIII. The applicant disagrees with the Examiner. The claims of Inventions IV, V, VI and VIII are related. Therefore, a search or examination of the claims can be made without unduly burdening the Examiner.

It is also asserted by the Examiner that Invention V is patentably distinct from Invention VII because the method can be used to generate a transgenic animal while the agent can be used to modulate glucocorticoid-induced receptor expression. The Applicant disagrees with the Examiner's assertion in that the claims of Invention V and Invention VII are related, and thus, a search or examination on those claims would not seriously burden the Examiner.

The Examiner further asserts that the claims of Inventions VI and VII are patentably distinct because the agent can be identified from *in vivo* assays using a transgenic animal harboring a disruption in glucocorticoid-induced receptor. The Applicant disagrees in that the claims of Inventions VI and VII are related and therefore a search or examination on those claims can be made without undue burden on the Examiner.

The Examiner also asserts that Inventions VII and VIII are patentably distinct because the agent of Invention VII can be used to modulate gene expression or gene product activity while the database of Invention VIII can be used for statistical analysis. The applicant disagrees with the Examiner. The claims of Inventions VII and VIII are related. Therefore, a search or examination of the claims can be made without unduly burdening the Examiner.

Although Applicant has provisionally elected Group III for purposes of advancing prosecution of the present application, Applicant contends, for the foregoing reasons, that the restriction requirement is improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the requirement.

A petition for the Extension of Time for the response to the Office Action for a period of three months from December 3, 2002 up to and including February 3, 2003 is submitted concurrently herewith.

Respectfully submitted,

Date: February 3, 2003

Aaron T. Hokamura (Reg. No. 51,810)

DELTAGEN, INC.
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Redwood City, CA 94063

(650) 569-5100

Enclosures

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/903,396	07/10/2001	Keith D. Allen	R-359	9463

7590 10/03/2002

DeltaGen, Inc.
740 Bay Road
Redwood City, CA 94063

FEB 19 2003

EXAMINER
BERTOGLIO, VALERIE E

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/03/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED 11-2-02

OCT 16 2002

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FEB 13 2003
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Office Action Summary	Application No.	Applicant(s)	
	09/903,396	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Valerie E. Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a nucleic acid construct and methods of making the construct, classified in class 536, subclass 23.1.

II. Claims 5-7, 9, 26, drawn to cells with a disruption in a glucocorticoid-induced receptor gene, classified in class 435, subclass 325.

III. Claims 8, 17-23, 25 and 33, drawn to a transgenic animal comprising a disruption in a glucocorticoid-induced receptor gene, classified in class 800, subclass 13.

IV. Claims 11, 12, 27-29, drawn to methods of using a transgenic animal comprising a disruption in an glucocorticoid-induced receptor gene to test agents, classified in class 800, subclass 3.

V. Claims 10 and 24, drawn to a method of making a transgenic animal, classified in class 800, subclass 21.

VI. Claims 13-15, 30, 31, drawn to methods of using cells with a disruption in a glucocorticoid-induced receptor gene to test agents, classified in class 435, subclass 325.

VII. Claims 16, 32 and 34, drawn to an agent, classified in class 530, subclass 350.

VIII. Claim 35, drawn to a database, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the nucleic acid construct can be used as a probe while the cells can be used in in vitro assays to determine agents that modulate glucocorticoid-induced receptor expression. Furthermore, the protocols and reagents required for the nucleic acid and the cells are materially distinct and separate. The burden required to search the nucleic acid construct and the cells together, each having materially different structures, would be undue.

Inventions I and III are patentably distinct because, the nucleic acid construct can be used as a probe while the transgenics can be used in in vivo assays to determine agents that modulate glucocorticoid-induced receptor expression. The burden required to search the nucleic acid construct and the transgenic together, each having materially different structures, would be undue.

Inventions I and IV are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The protocols and reagents required for the nucleic acid and using the transgenics are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the methods together, each having materially different structures, would be undue.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid construct can be used as a DNA probe.

Inventions I and VI are patentably distinct because, the nucleic acid construct can be used as a probe while the method can be used in *in vitro* assays to determine agents that modulate glucocorticoid-induced receptor expression. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The construct does not require the methods and the methods do not require the construct. Furthermore, the burden required to search the nucleic acid construct and the method together, each having materially different structures, would be undue.

Inventions I and VII are patentably distinct because, the nucleic acid construct can be used as a probe while the agent can be used to modulate glucocorticoid-induced receptor expression. The protocols and reagents required for the nucleic acid and the agent are materially distinct and separate. The construct does not require the agent and the agent does not require the construct. Furthermore, the burden required to search the nucleic acid construct and the agent together, each having materially different structures, would be undue.

Inventions I and VIII are patentably distinct because the nucleic acid construct can be used as a probe while the database of invention VIII can be used for statistical analysis. The nucleic acid construct is not necessary for the database nor is the

database necessary for the nucleic acid construct. The burden required to search invention II and VIII together would be undue.

Inventions II and III are patentably distinct because, the cells can be used in in vitro assays to determine differential gene expression while the transgenics can be used in in vivo assays to determine agents that modulate glucocorticoid-induced receptor expression. Furthermore, the protocols and reagents required for the cells and the transgenics are materially distinct and separate. The burden required to search the cells and the transgenic together, each having materially different structures, would be undue.

Inventions II and IV are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the method can be used in *in vivo* assays to determine agents that modulate glucocorticoid-induced receptor expression. The protocols and reagents required for the cells and methods of using the transgenic are materially distinct and separate. The cells do not require the methods and the methods do not require the cells. Furthermore, the burden required to search the cells and the method of using a transgenic together, each having materially different structures, would be undue.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can be

used for in vitro assays to determine agents that modulate glucocorticoid-induced receptor expression.

Inventions II and VI are related as product and process of use. In the instant case the method of testing agents can be done *in vivo* using transgenics comprising a disruption in glucocorticoid-induced receptor while the cells can be used in *in vitro* assays to determine differential gene expression between cells with a disruption in glucocorticoid-induced receptor and wild type cells.

Inventions II and VII are patentably distinct because, the cells can be used in *in vitro* assays to determine differential gene expression while the agent can be used to modulate glucocorticoid-induced receptor expression. The cells do not require the agent and the agent does not require the construct. Furthermore, the burden required to search the cells and the agent, each having materially different structures, would be undue.

Inventions II and VIII are patentably distinct because the cells of invention II can be used to isolate protein while the database of invention VIII can be used for statistical analysis. The cells are not necessary for the database nor is the database necessary for the cells. The burden required to search invention II and VIII together would be undue.

Inventions III and IV are related as product and process of use. In the instant case the method of testing agents can be done *in vitro* using cells comprising a disruption in glucocorticoid-induced receptor. Furthermore, the transgenic can be used to determine the role of glucocorticoid-induced receptor in vivo.

Inventions III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the transgenic can be made by injecting the blastocyst with DNA.

Inventions III and VI are patentably distinct because the transgenics can be used to determine the role of glucocorticoid-induced receptor in vivo while methods of using the cells are process steps with the purpose of identifying agents. Furthermore, the protocols and reagents required for the transgenics and the methods are materially distinct and separate. The burden required to search the transgenic and the methods of using cells together, each having materially different structures, would be undue.

Inventions III and VII are patentably distinct because the transgenics can be used to determine the role of glucocorticoid-induced receptor in vivo while the agent is used to modulate glucocorticoid-induced receptor. The protocols and reagents required for the transgenics and the agent distinct and separate. The burden required to search the transgenic and the agent together, each having materially different structures, would be undue.

Inventions III and VIII are patentably distinct because the methods of invention III can be used make a nucleic acid construct while the database of invention VIII can be used for statistical analysis. The nucleic acid construct is not necessary for the

database nor is the database necessary for the nucleic acid construct. The burden required to search invention III and VIII together would be undue.

The methods of each of inventions IV-VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The purpose of Inventions IV-VI is different. The transgenic used in Invention IV is not required for the methods of Inventions V or VI. The burden required to search Inventions IV-VI together would be undue.

Inventions IV and VII are patentably distinct because, the agent can be identified from in vitro assays using cells harboring a disruption in glucocorticoid-induced receptor. The agent does not require the methods of using the transgenic and the methods do not require the agent. Furthermore, the burden required to search the transgenic and the agent, each having materially different structures, would be undue.

Inventions IV, V, or VI and invention VIII are patentably distinct because the methods of inventions IV, V, or VI do not require the database of invention VIII and the database does not require the methods. The burden required to search inventions IV, V, or VI and invention VIII together would be undue.

Inventions V and VII are patentably distinct because, the method can be used to generate a transgenic animal while the agent can be used to modulate glucocorticoid-induced receptor expression. The protocols and reagents required for the transgenic and the agent are materially distinct and separate. The transgenic does not require the agent and the agent does not require the construct. Furthermore, the burden required to

search the transgenic and the agent, each having materially different structures, would be undue.

Inventions VI and VII are patentably distinct because, the agent can be identified from in vivo assays using a transgenic animal harboring a disruption in glucocorticoid-induced receptor. The agent does not require the methods of using the cells and the methods do not require the agent. Furthermore, the burden required to search the cells and the agent, each having materially different structures, would be undue.

Inventions VII and VIII are patentably distinct because the agent of invention VII can be used to modulate gene expression or gene product activity while the database of invention VIII can be used for statistical analysis. The agent is not necessary for the database nor is the database necessary for the agent. The burden required to search invention VII and VIII together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL [illegible] WILSON
PATENT EXAMINER